IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA; and THE STATE OF NEW YORK *ex rel.* DR. ANTONI NARGOL & DR. DAVID LANGTON Plaintiffs-Relators, v. DEPUY ORTHOPAEDICS, INC., DEPUY, INC., and JOHNSON & JOHNSON SERVICES, INC., Defendants.	Case No. 12-10896-LTS

DEFENDANTS DEPUY ORTHOPAEDICS, INC., DEPUY INC., AND JOHNSON & JOHNSON SERVICES, INC.'S MOTION FOR PHASED DISCOVERY

Defendants DePuy Orthopaedics, Inc. (now Medical Device Business Services, Inc.), DePuy, Inc. (now DePuy Synthes Inc.), and Johnson & Johnson Services, Inc. (together "Defendants"), respectfully submit this motion for phased discovery. Defendants seek phased discovery as to whether the Relators failed to disclose "all material evidence and information" they possessed to the Government related to the Pinnacle MoM prior to filing this *qui tam* suit as required by 31 U.S.C. § 3730(b)(2) ("statutory bar"), and whether the Relators' claims are barred by the False Claims Act's ("FCA") public disclosure bar, 31 U.S.C. § 3730(e)(2)(4)(A)-(B). For the following reasons, phased discovery and the subsequent filing of a motion for summary judgment on the application of the FCA's disclosure provisions is warranted.[1]

[1] This motion is limited to five pages of text in light of this Court's November 20, 2017 order (Dkt. No. 234).

1. Local Rules 26.3 and 16.1(d)(1)(b) encourage the implementation of a staged discovery process where conducting narrow discovery on a threshold issue would "facilitate settlement and the efficient completion of discovery." The Defendants respectfully suggest that the facts of this case, when applied to the relevant law, support the conclusion that a dispositive motion based on the Relators' failure to overcome the FCA's statutory bar and public disclosure bar will follow a period of phased discovery.[2]

2. The Defendants believe that discovery will show that the Relators failed to provide the Government with a "written disclosure of substantially all material evidence and information the person possesses" as to the Pinnacle MoM at the time this *qui tam* action was filed.[3] *See* 31 U.S.C. 3730(b)(2). Failure to comply with the disclosure requirement in Section 3730(b)(2) warrants dismissal of this *qui tam* action with prejudice. *See, e.g., United States ex rel. Pilon v. Martin Marietta Corp.*, 60 F.3d 995, 998-1000 (2d Cir. 1995).

3. Separately, the public disclosure bar states, in part, that "[t]he court shall dismiss an action or claim . . . if substantially the same allegations . . . were publicly disclosed" in mediums including a "Federal report, hearing, audit or investigation[] or from the news media[]" unless the Relators are original sources. 31 U.S.C. § 3730(e)(2)(4)(A)(ii)-(iii). Original sources are defined as individuals who, *prior to the public disclosure*, "voluntarily disclosed to the Government the information on which allegations . . . in a claim are based" or provide

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[2] In order to avoid "fishing expeditions" by plaintiffs-relators, courts have cabined discovery in the FCA context. *See, e.g., United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 719 F.3d 31 (1st Cir. 2013) (limiting discovery to threshold questions, including public disclosure questions); *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 17 (D. Mass. 2008) (limiting discovery initially to a discrete region to examine validity of allegations before expanding discovery nationwide); *United States ex rel. Carpenter v. Abbott Labs., Inc*., 723 F. Supp. 2d 395, 409–10 (D. Mass. 2010) (following the "sensible course" of Rost in its discovery order); *United States v. Coloplast Corp.*, No. 11-12131-RWZ (D. Mass.) (Dkt. # 252) (Feb. 3, 2017 Order) (approving joint discovery plan "with Defendant's position that discovery be phased," where initial phase was limited to potentially case-dispositive materiality issue (Dkt. # 226, 242)).

[3] For example, the Relators allege in Paragraph 43 of the SAC that they did not discover the "surface roughness" defect until 2014 – three years after the original complaint in this case was filed.

information that is "independent of or materially adds to the publicly disclosed allegations" *and have provided the information to the Government before filing suit*. *Id*. § 3730(e)(2)(4)(B). Here, the relevant allegations are those contained in the Relators' corrected Second Amended Complaint ("SAC"), not the Relators' initial or First Amended Complaint. *See Rockwell Intern. Corp. v. United States*, 549 U.S. 457, 473 (2007). Given the long evolution of this matter from an ASR-centric case to a Pinnacle MoM case, the Defendants believe that the Relators' Pinnacle MoM allegations were publicly disclosed prior to the filing of the SAC and that the Relators do not fall within the original source exception to the public disclosure bar.

4. This case is particularly ripe for phased discovery given the matter's unique procedural background, the status of the Relators as expert witnesses, the continued sealing of the Relators' original complaint, and the Relators' prior use of protected documents to write their First Amended Complaint. The Relators ultimately sought to circumvent the taint of their First Amended Complaint by changing the focus of the SAC to claims regarding the Pinnacle MoM, rather than the ASR device. Additionally, the Relators serve as expert witnesses in long-running products liability matters around the world that raise the same or similar issues regarding the Pinnacle MoM. Such facts warrant a phased stage of discovery that focuses on the source of the Relators' allegations, to whom within the government those allegations were disclosed by the Relators, when they were disclosed, and when the same allegations were publicly raised or otherwise discovered by the government.[4]

5. Evidence supporting the Defendants' contention that the Relators' claims are barred by a prior government audit or investigation can be taken from the Relators' SAC itself.

[4] *See, e.g., United States ex rel. Wilson v. Bristol Myers Squibb, Inc.*, No. 06cv12195-NG, 2011 WL 2462469, at *7 (D. Mass. June 16, 2011) (dismissing case, in part, on public disclosure grounds where relator failed to voluntarily disclose his information to the government prior to time the original complaint was filed).

There, the Relators' allege that the FDA conducted a thorough inspection of DePuy's Warsaw, Indiana Facility in May 2011, where the "FDA's inspection found that thirty-three Pinnacle metal liners were out of conformance" . . . [and that] [t]he [FDA] Report states that "33 of metal liners produced *fell below the lower specification limit*." *Id.* ¶ 320 (emphasis added). The Defendants believe that targeted discovery will demonstrate that the manufacturing defect claims the Relators allege were known to the FDA prior to the filing of the SAC.[5]

6. Furthermore, information regarding purported defects involving DePuy's Pinnacle MoM devices was publicly disclosed in advance of the Relators' SAC. "Allegations of fraud are publicly disclosed when they are 'placed in the public domain.' While the allegations need not be accessible to all members of the public, they must be disseminated beyond the inner precincts of government itself." *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112, 120 (D. Mass. 2011) (citation omitted). Moreover, "'courts have construed the term [news media] to include readily accessible websites.'" *United States ex rel. Green v. Service Contract Educ. & Training Trust Fund*, 843 F.Supp.2d 20, 32 (D.D.C.2012) (and collecting cases). Publication in newspapers or scholarly scientific periodicals places the Relators' allegations into the public sphere.[6] *See, e.g., United States ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 463 (S.D.N.Y. 2002). So long as the material elements of an alleged fraud are in the public domain, "a complaint that targets a scheme previously revealed through

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[5] *See, e.g., Bellevue v. Universal Health Servs. of Hartgrove, Inc.*, 867 F.3d 712, 719 (7th Cir. 2017) (finding that government "audit report[s] and letters" constituted a "public disclosure" within the meaning of the FCA); *Gross v. AIDS Research Alliance-Chicago*, No. 01 C 8182, 2004 WL 905952, at *7 (N.D. Ill. Apr. 27, 2004) (finding that FDA warning letter constituted a "public disclosure because it establishes the agency's awareness of the information that substantiates [the relator's] allegation of fraud").

[6] *See, e.g.*, Barry Meier, *Concerns Over Metal on Metal Hip Implants*, N. Y. Times, Mar. 3, 2010, *available at* http://www.nytimes.com/2010/03/04/health/04metalhip.html (asserting that some metal-on-metal hip implants may be poorly designed and identifying DePuy Orthopaedics as a manufacturer of metal-on-metal hip implants). For the purposes of this five-page motion, the Defendants have not detailed the litany of relevant public disclosures, either in the news media or in the context of FDA audits or reviews.

public disclosures [will be] barred even if it offers greater detail about the underlying conduct. *United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 210 (1st Cir. 2016).

7. A motion for summary judgment is the appropriate vehicle for the Defendants to assert that the Relators' claims are barred by the public disclosure bar. In the wake of the 2009 FCA Amendments, the First Circuit has strongly implied that the public disclosure bar is no longer jurisdictional. *See Winkelman*, 827 at 203 n.3 ("Even though we do not pass upon the question of whether Congress has stripped the public disclosure bar of its jurisdictional character, the arguments for that proposition are strong."). Accordingly, a motion to dismiss on public disclosure grounds must be analyzed under Rule 12(b)(6). *See id.* The challenges this raises to a court's inquiry are plain: inevitably any public disclosure bar/original source analysis will be fact-specific and rely upon documents that fall outside the scope of a Rule 12(b)(6) inquiry. Discovery is necessary to allow a full and fair inquiry into the Defendants' contention that the Relators' claims are precluded by the public disclosure bar.

8. Accordingly, narrow and focused discovery on the application of the statutory disclosure requirement and public disclosure bar, and the subsequent filing of a dispositive motion regarding the same, would significantly curb the burden and expenditure of time and resources for the Defendants, the Relators, and the Court. The Defendants anticipate making the following discovery requests, among others:

a. Document requests, interrogatories, and RFAs that focus on 1) information from the Relators and other sources evidencing when they began to discover alleged defects with the Pinnacle MoM; 2) information from the Relators and other sources evidencing the source of the allegations in the SAC; 3) information from the Relators and other sources evidencing communications with United States governmental entities regarding alleged defects with the Pinnacle MoM; and 4) all documents and information provided to the U.S. Attorney's Office and/or Department of Justice in connection with the Relators' Section 3730(b)(2) disclosure;

b. Depositions of the Relators and other sources focusing on the above topics; and

c. The Defendants also will seek to partially unseal the original complaint in this matter, which the Defendants have not yet seen, in order to determine the scope of allegations initially made by the Relators.

9. The Defendants believe that narrow and focused discovery on the application of the public disclosure bar and original source exception could be completed no later than March 30, 2018. A corresponding motion for summary judgment would be filed no later than April 13, 2018.

10. For the foregoing reasons, the Defendants request that this Court grant the Defendant's motion for phased discovery.

Respectfully submitted,

DEFENDANTS
DEPUY ORTHOPAEDICS, INC., DEPUY, INC., JOHNSON & JOHNSON SERVICES, INC.

By their attorneys,

/s/ Mark D. Seltzer.

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CERTIFICATE PURSUANT TO LOCAL RULE 7.1

Pursuant to Local Rule 7.1(a)(2), I hereby certify that counsel for Plaintiff-Relators Antoni Nargol and David Langton and counsel for Defendants DePuy Orthopaedics, Inc. (now Medical Device Business Services, Inc.), DePuy, Inc. (now DePuy Synthes, Inc.), and Johnson & Johnson & Johnson Services, Inc., have conferred in good faith in an effort to narrow or resolve the issues raised in this motion and that counsel for the Relators have indicated that they do not consent to this motion.

/s/ Hannah R. Bornstein
Hannah R. Bornstein

CERTIFICATE OF SERVICE

I hereby certify that on December 8, 2017, I electronically filed the foregoing document with the United States District Court for the District of Massachusetts by using the CM/ECF system. I certify that the following parties or their counsel of record are registered as ECF Filers and that they will be served by the CM/ECF system:

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